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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/755,187	01/08/2001	Mike Farwick	P 275573 990219BT	4866

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PILLSBURY WINTHROP LLP
1600 TYSONS BOULEVARD
MCLEAN, VA 22102

EXAMINER
FRONDA, CHRISTIAN L

ART UNIT	PAPER NUMBER
1652	10

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/755,187	Farwick et al.
Examiner	**Art Unit**
Christian L. Fronda	1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____ .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-17 is/are pending in the application.

4a) Of the above, claim(s) 8-17 is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☒ Claim(s) 1-7 is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group I in Paper No. 7 is acknowledged. The traversal is on the grounds that a search of all the claims would not be a serious burden. This is not found persuasive because as stated in the previous Office Action each of the processes of Groups II-VI are distinct both physically and functionally and require different process steps, reagents, and parameters. A search of all the inventions in the patent literature and the non-patent literature cannot be made without serious burden because the inventions require separate searches that have different limits, boundaries, scope, and subject matter.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-7 are under consideration in this Office Action.

Claim Objections

3. Originally filed claims 6-8 are objected to because the originally filed claims omitted claim 5. Appropriate correction is required. For examination purposes originally filed claims 6-8 are renumbered as claims 5-7.

Claim Rejections - 35 U.S.C. § 101

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 1-7 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible asserted utility or a well established utility.

Applicants disclose the nucleotide sequences of SEQ ID NO: 1 and the deduced amino acid sequence of the protein encoded as the amino acid sequence of SEQ ID NO: 2. Applicants disclose that the protein of SEQ ID NO: 2 is a component of a phosphotransferase system which is a generic asserted utility. The specification does not specifically disclose the specific function

of the protein of SEQ ID NO: 2 or its relationship to any disease. It appears that the main utility of the nucleic acid and protein is to carry out further research to identify the biological function and possible diseases associated with the protein. Substantial utility defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utility. Thus, the claimed invention has no specific or substantial asserted utility.

Applicant is referred to the revised interim guidelines concerning compliance with 35 U.S.C. 101, published in the Official Gazette and also available at www.uspto.gov.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible asserted utility or a well established utility for the reasons set forth above in the rejection of claims 1-7 under 35 U.S.C. 101, one skilled in the art clearly would not know how to use the claimed invention.

Furthermore, the specification does not reasonably provide enablement for any isolated polynucleotide which is at least 70% identical to a polynucleotide coding for a polypeptide containing the amino acid sequence of SEQ ID NO: 2. Factors to be considered in determining whether undue experimentation is required, are summarized In re Wands [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The nature and breadth of the claims encompasses any isolated polynucleotide which is at least 70% identical to a polynucleotide coding for a polypeptide containing the amino acid sequence of SEQ ID NO: 2. While molecular biological techniques and genetic manipulation techniques are known in the prior art and the skill of the artisan are well developed, knowledge regarding the biological function, biological activity, or utility of any isolated polynucleotide which is at least 70% identical to a polynucleotide coding for a polypeptide containing the amino acid sequence of SEQ ID NO: 2 is lacking. Thus, searching for the biological function, biological

activity, or utility of said polynucleotide is well outside the realm of routine experimentation and predictability in the art of success in determining the biological function, biological activity, or utility of said polynucleotides is extremely low. The amount of experimentation to determine the biological function, biological activity, or utility of said polynucleotides is enormous and entails screening a vast number of organisms for an organism that contains the claimed polynucleotide and searching for the biological function, biological activity, or utility of the polynucleotide.

Since routine experimentation in the art does not include screening vast numbers of polynucleotides which encode polypeptides having at least 70% identity to the amino acid sequence of SEQ ID NO:2, where the expectation of obtaining a desired biological function, biological activity, or utility is unpredictable, the Examiner finds that one skilled in the art would require additional guidance, such as information regarding the structure and function relationship of the claimed polynucleotides. Without such a guidance, the experimentation left to those skilled in the art is undue.

8. Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to any polynucleotide that is at least 70% identical to any polynucleotide encoding the amino acid sequence of SEQ ID NO: 2, any polynucleotide that encodes a polypeptide containing an amino acid sequence that is at least 70% identical to the amino acid sequence of SEQ ID NO: 2, any polynucleotide encoding a polypeptide comprising SEQ ID NO: 2, or any polynucleotide comprising SEQ ID NO: 1. The specification, however, only provides a single representative species encompassed by these claims: a polynucleotide consisting of the nucleotide sequence of SEQ ID NO: 1. There is no disclosure of any particular structure to function/activity relationship in the single disclosed species. The specification also fails to describe additional representative species of these polynucleotides by any identifying structural characteristics or properties for which no predictability of structure is apparent. Given this lack of additional representative species as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and

distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1-4, 6, and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, the phrase "at least 70% identical to a polynucleotide coding for a polypeptide that contains the amino acid sequence of SEQ ID NO: 2" renders the claim vague and indefinite because the specific nucleotide sequence/structure of the polynucleotide encoding SEQ ID NO: 2 is not known and not recited in the claim. Claims 2, 3, 6, and 7 which depend from claim 1 is also rejected because they do not correct the defect of claim 1.

In claim 2, the phrase "preferably recombinant DNA which is capable of replication in coryneform bacteria" renders the claim vague and indefinite because it is unclear whether the limitations following the word "preferably" are part of the claimed invention (see MPEP § 2173.05(d)).

In claim 4 (ii), the phrase "within the degeneracy region of the genetic code" renders the claim vague and indefinite because the meaning of the phrase is not known and the specific nucleotides that are to be changed in the claimed polynucleotide which are "within the degeneracy region of the genetic code" are not known.

In claim 4 (iii) the phrase "which hybridizes with the sequence" renders the claim vague and indefinite because the specific hybridization conditions are not known and not recited in the claim.

In claim 4 (iv) the phrase "functionally neutral sense mutations" renders the claim vague and indefinite because the meaning of the phrase is not known and the specific mutations to specific nucleotides which would produce "functionally neutral sense mutations" are not known and not recited.

Claim Rejections - 35 U.S.C. § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Zhu et al.

Claim 1 is anticipated by Zhu et al. (Accession L22432) since Zhu et al. teach a polynucleotide sequence containing at least 15 consecutive nucleotides of a polynucleotide that encodes the amino acid sequence of SEQ ID NO: 2 (see Alignment No. 1).

13. Claim 4 is rejected under 35 U.S.C. 102(b) as being anticipated by Oliver et al.

Claim 4 is anticipated by Oliver et al. (Accession AL009204) since Oliver et al. teach a polynucleotide sequence that will hybridize to SEQ ID NO: 1 at low stringency conditions (see Alignment No. 2).

Conclusion

14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (703)305-1252. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703)308-3804. The fax phone number for this Group is (703)308-0294. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703)308-0196.

CLF

PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600